IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA
ex rel. LAUREN KIEFF

Plaintiffs,

SEALED

VS.

WYETH PHARMACEUTICALS, INC.

Defendant.

CIVIL ACTION NO. 03-12366DPW

MAGISTRATE JUDGE Alexander

FILED UNDER SEAL

PLAINTIFF'S ORIGINAL COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *et seq.*

1. The *qui tam* Relator, Lauren Kieff ("Relator"), on behalf of the United States of America, brings this action against Wyeth Pharmaceuticals, Inc. ("Wyeth") for violations of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act.

I.
SUMMARY OF THE ACTION

2. This case involves a class of drugs known as proton pump inhibitors, or PPIs. PPIs are generally used to treat gastroesophageal reflux disease (GERD), a disease characterized by frequent, persistent heartburn and acid regurgitation which possibly may result in damage to the esophagus or other complications. Before prescribing a PPI drug, doctors often recommend that patients suffering from the symptoms of heartburn try lifestyle modifications and over-the-counter medications such as Tagamet, Pepcid or Zantac (H-2 Blockers).

3. The first proton pump inhibitor, AstraZeneca Pharmaceuticals, LP's ("AstraZeneca") Prilosec[1] (omeprazole), became available in the United States in 1989, followed by the introduction of Takeda Chemical Industries/Abbott Laboratories' Prevacid (lansoprazole) in 1995 and Janssen Pharmaceutical Products, LP's Aciphex (rabeprazole sodium) in 1999. Wyeth's PPI-class drug at issue in this complaint is Protonix (pantoprazole) which was launched in tablet form (Protonix Oral) in May 2000 and in intravenous form (Protonix I.V.) in or about June 2001.

4. The relevant National Drug Codes (NDCs) for Protonix Oral and I.V. are as follows:

Protonix Oral:	00008-0843-81
	00008-0841-81
	00008-0841-99
Protonix I.V.:	00008-0923-03

5. Wyeth launched Protonix Oral in mid-2000 in an extremely tight and competitive PPI market dominated by Prilosec and Prevacid (and in 2001 by AstraZeneca's Nexium, its second PPI drug). At the time, these two drugs – Prilosec and Prevacid – already controlled over 55 and 40 percent of the market, respectively. As a result, sales of Protonix Oral suffered. Sales of Protonix Oral in 2000[2] – $145 million – were dwarfed by Prilosec sales for 2000 of over $4.6 billion.

6. Prilosec's market dominance and strong sales continued throughout 2001. Moreover, in or about March of 2001, AstraZeneca began an aggressive nominal pricing campaign to launch its second generation PPI drug, Nexium, to hundreds of teaching hospitals nationwide. In contrast, for the first quarter of 2001, Protonix Oral sales continued to be weak. Faced with a very small

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[1] Currently Prilosec is available over-the-counter in generic form for the treatment of heartburn, but not for other conditions such as esophagitis.

[2] For the approximately six months it was available that year.

market share and AstraZeneca's nominal pricing strategy for Nexium, Wyeth quickly responded with its own nationwide nominal pricing campaign for Protonix Oral, offering the Protonix 40 mg tablet at just $0.15 per tablet (as communicated to Relator by many hospital pharmacists) versus a reported price of $2.50 per pill. And, unlike the Nexium nominal pricing campaign, nominal pricing on Protonix Oral was not only offered to teaching institutions but to for-profit and not for-profit hospitals as well. In short, Wyeth used nominal pricing as a marketing ploy rather than for charitable or research-oriented purposes.

7. In or about June of 2001, Wyeth introduced Protonix I.V., the first and only intravenous PPI drug on the market for the treatment of GERD in patients who cannot take oral PPI medications (there are I.V. formulations of H-2 Blockers, such as Pepcid I.V. and Zantac I.V. on the market in the United States, but not any other I.V. PPI drugs).

8. In or about June of 2001, Wyeth embarked on a campaign to bundle sales of its Protonix I.V. drug with its flagging Protonix Oral drug and to offer nominal pricing and/or deeply-discounted pricing on these bundled sales of its drugs to hospitals. This bundling scheme was a tacit recognition on Wyeth's part that sales of Protonix I.V., which is prescribed on a short term basis, should be leveraged to encourage sales of Protonix Oral, which is routinely prescribed on a long term basis, often for many years after a patient has been discharged from the hospital. Thus, the real money was to be found in Protonix Oral sales. Further, when Protonix I.V. was launched in mid-2001, Wyeth began to promote Protonix I.V. for off-label uses, thus further increasing demand for the I.V.

9. The above marketing tactics were highly successful – according to Wyeth's 2002 Annual Report, Protonix sales in 2002 topped $1 billion and represented 15% of the fiercely competitive national PPI market. In the Boston area, as a result of the success of the Protonix Oral and I.V. marketing campaign, market share in the first quarter of 2003 for Protonix was 35% in the Partners HealthCare Network and 46% in the CareGroup Healthcare System. These two healthcare networks are among the very largest in the Boston area. Currently, the nationwide market share for Protonix is approximately 17%.

10. As alleged herein, in selling and marketing Protonix, Wyeth knowingly defrauded the Federal Health Care Programs by: 1) offering and providing nominally priced and/or heavily-discounted Protonix Oral and I.V. to hospitals as a disguised kickback financed by the Federal Health Care Programs' reimbursement, including Medicare and Medicaid (*see* section V.B. below); 2) submitting false price representations for Protonix Oral and I.V. resulting in inflated reimbursement by the Federal Health Care Programs, including Medicare and Medicaid (*see* section V.C. below); 3) underpaying its rebate obligations under the Medicaid Rebate Program by failing to properly allocate for bundled sales of Protonix Oral and I.V. (*see* section V.D. below); and 4) marketing Protonix I.V. for off-label uses (*see* section V.E. below). In so doing, Defendant has caused the submission of false claims to the Federal Government and has made false statements and records to the Federal Government to decrease the rebates due under the Medicaid Rebate Program.

II.
THE PARTIES

11. The party in this action is the UNITED STATES. At all times material to this civil action, the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and its successor agency the Centers for Medicare and

Medicaid Services ("CMS") and the Bureau of Program Operations ("B.P.O.") were agencies and instrumentalities of the UNITED STATES and their activities, operations and contracts in administering the Medicare and Medicaid Programs were paid from United States Funds.

12. Defendant, Wyeth Pharmaceuticals, Inc., is a corporation organized under the laws of Pennsylvania and headquartered in Collegeville, Pennsylvania. Wyeth Pharmaceuticals, Inc. holds itself out as a division of, and is wholly-owned by, Wyeth, Inc., a corporation organized under the laws of Delaware. To the extent the acts of Wyeth Pharmaceuticals, Inc. at issue herein were performed by or otherwise attributable to Wyeth, Inc., or any subsidiary or affiliate of it, then judgment should be entered against Wyeth, Inc. where appropriate. Wyeth Pharmaceuticals, Inc. and Wyeth, Inc. are referred to collectively herein as "Wyeth" or "Defendant". At all times material to this civil action, Wyeth has transacted business in the Federal Judicial District of Massachusetts by, including but not limited to, selling and distributing its drugs, including those identified in this Complaint, to purchasers within the District of Massachusetts.

13. Relator, Lauren Kieff, is a citizen of the United States and a resident of the Commonwealth of Massachusetts. Relator has standing to bring this action pursuant to 31 U.S.C. §3730(b)(1).

14. Ms. Kieff received her undergraduate degree from the University of Pennsylvania and a Master's Degree in Public Health from Boston University School of Public Health. From 1989 through the present (with a 10 month hiatus to earn her Master's Degree), Relator has been employed by AstraZeneca Pharmaceuticals, LP ("AstraZeneca") in positions ranging from hospital sales representative to medical information scientist covering regional and national managed care accounts. In her current position as a hospital-based pharmaceutical sales specialist, she participates

in the sale of gastrointestinal and cardiovascular AstraZeneca drug products to teaching institutions located in Massachusetts (Boston area) and Rhode Island. In the course of her employment, Relator has had direct communications with the pharmacy departments and/or medical specialists of various teaching institutions such as Tufts-New England Medical Center, Brigham and Women's Hospital, Massachusetts General, Beth Israel Deaconess Medical Center and Rhode Island Hospital concerning the decision to purchase PPI drugs such as Prilosec, Prevacid, Aciphex and Protonix as well as internal discussions with AstraZeneca sales and marketing people. Such communications have made her privy to various marketing methods being utilized by companies manufacturing PPI drugs. Through her employment at AstraZeneca, Relator has uncovered the False Claims Act violations against Wyeth detailed herein.

III.
JURISDICTION AND VENUE

15. Jurisdiction is founded upon the Federal False Claims Act (the "Act" or the "False Claims Act"), 31 U.S.C. § 3729 *et seq.*, specifically 31 U.S.C. § 3732, and also 28 U.S.C. §§ 1331, 1345, and is not barred by § 3730(e). The information upon which these allegations are based was voluntarily provided by Relator to the Federal Government prior to filing this Complaint pursuant to 31 U.S.C. §§ 3730(e)(4)(B) and 3730(b)(2). No public disclosure of the allegations or transactions on which this action is based occurred before the filing of this Complaint, and this action is not based upon a public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report hearing, audit, or investigation, or from the news media. In the alternative, should the court find that there was a public disclosure of such allegations or transactions before the filing of this action, and that this action is based on a public disclosure of such allegations or transactions, then Relator is an

original source of the information on which any such publicly disclosed allegations or transactions are based, and has direct and independent knowledge of such information, and voluntarily provided the information to the Government before filing this action.

16. Venue in the District of Massachusetts is appropriate under 31 U.S.C. § 3732(a) and sufficient contacts exist for jurisdiction in that Defendant conducts business and sells its pharmaceuticals, including those identified in this Complaint, in the District of Massachusetts. Such drugs, as Defendant knows, 1) have been and continue to be supplied to Federal Health Care Program recipients, including Medicare and Medicaid recipients and 2) have been and continue to be the subject of claims for reimbursement made by Federal Health Care Program drug providers, including hospitals and pharmacies.

17. A copy of this initial Complaint and written disclosures of substantially all material evidence and information Relator possesses was served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure, prior to the filing of this Complaint *in camera* and under seal by delivering a copy of this Complaint, material evidence and information to the United States Attorney for the District of Massachusetts and by sending a copy of this Complaint, material evidence and information by certified mail to the Attorney General of the United States in Washington, District of Columbia.

IV.

BACKGROUND REGARDING THE RELEVANT FEDERAL HEALTH CARE PROGRAMS

18. The Federal health care programs referred to herein ("Federal Health Care Programs") are defined as follows (consistent with the definition provided in 42 U.S.C. § 1320a-7b(f)): "any plan or program that provides health benefits, whether directly, through insurance, or

otherwise, which is funded directly, in whole or in part, by the United States Government" including, among others, Medicare, Medicaid and CHAMPUS.

A. The Medicare Program

19. The United States, through the Department of Health and Human Services ("HHS"), administers the Hospital Insurance Program for the Aged and Disabled established by Part A and the Supplementary Medical Insurance Program established by Part B, Title XVIII, of the Social Security Act under 42 U.S.C. §§ 1395 *et seq.* (the "Medicare Program").

20. The Medicare Program is the federally financed health insurance system for persons who are aged 65 and over and for those who are disabled. Medicare makes payments under Part A and Part B using private companies and insurance companies who provide these services under a contract with CMS, the Centers for Medicare and Medicaid Services (formerly HCFA).

21. At all relevant times, Wyeth's Protonix Oral was a covered Medicare Program benefit when provided to a Medicare recipient in an in-patient setting. However, when prescribed by a doctor to a Medicare beneficiary on an out-patient basis, the cost of Protonix Oral was generally not reimbursed by Medicare although exceptions exist, in certain instances, as in the case of some patients in nursing home facilities. At all relevant times, the cost of Wyeth's Protonix I.V. was covered by Medicare when provided to a Medicare recipient in both the in-patient as well as the out-patient setting.

22. When hospitals provide either Protonix Oral or Protonix I.V. on an in-patient basis to Medicare beneficiaries, they are paid set amounts from the Medicare program based on the nature of the illness being treated. Such amounts encompass, among other items, payment for any drugs administered.

B. The Medicaid Program

23. The United States Government partially funds state sponsored medical assistance programs for the poor pursuant to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Enacted in 1965, the Medicaid Program functions as a jointly-funded cooperative undertaking between the Federal and State Governments. Each State administers its own Medicaid program, but the State's programs are governed by Federal statutes, regulations and guidelines.

24. Benefits for drugs are optional but all States have opted to provide Medicaid drug reimbursement coverage.

25. The Federal portion of States' Medicaid payments, the Federal Medical Assistance Percentage ("FMAP"), is based on a State's per capita income compared to the national average. The Federal portion consists of a minimum of 50% up to a maximum of 83%.

26. The States (and the District of Columbia) are required to implement a State Health Plan containing certain specified minimum criteria for coverage and payment of claims in order to qualify for Federal funds for Medicaid expenditures. 42 U.S.C. § 1396a(a)(30)(A).

27. At all relevant times, the cost of providing Wyeth's Protonix Oral and I.V. drugs to Medicaid recipients was covered by many States' Medicaid Programs.

C. The Medicaid Rebate Program

28. After hearings in 1989, Congress concluded that the Federal government, as the largest payor for prescription drugs, was paying significantly more under the State's Medicaid Programs than certain private payors. *See, e.g., Skyrocketing Drug Prices: Hearings Before the Special Committee on Aging,* United States Senate, 101st Congress, 290-297 (1989).

29. Congress addressed this inequity in 1990, by establishing the Medicaid Rebate Program (also referred to herein as the "Rebate Program"). The stated purpose of the Rebate Program was to give the State Medicaid Programs the "benefit of the best price for which a manufacturer [sold] a prescription drug to any ... private purchaser." H.R. Rep. 101.881 at 96 (1990). Under the Rebate Program, in order for a manufacturer's drug to be reimbursed by Medicaid, the manufacturer must enter into a Rebate Agreement with the Secretary of Health and Human Services. With respect to single source or innovator multiple source drugs under such an agreement, the manufacturer agrees to sell its drug to the Medicaid program at its best price by paying each State a quarterly rebate. 42 U.S.C. § 1396 *et seq.* At all times relevant herein, Protonix Oral and I.V. have been single source or innovator multiple source drugs.

30. Under the Rebate Program, "Best Price" or "BP" generally means the "lowest price available from the manufacturer . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity" and includes cash discounts, free goods, volume discounts and rebates.

31. Bundled sales, such as those at issue in this action, are sales in which the condition for a rebate or discount to be given is that two or more drugs are purchased together, or in which the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately. Bundled sales are a common industry practice among drug manufacturers.

32. Pursuant to Medicaid regulations and the terms of the Rebate Agreement entered into between drug manufacturers and the Secretary of Health and Human Services, for Best Price calculations in the context of bundled sales, the discount must be allocated proportionally to the dollar value of the units of each drug sold under the bundled agreement.

33. The amount received by a State in Medicaid rebates is considered a reduction in the total amount expended under any given State's plan. Therefore, the less any given State receives in Medicaid rebates, the greater the total amount expended by the State and the more the Federal Government must correspondingly pay to each State (the FMAP). 42 U.S.C. § 1396b(a)(1); 42 U.S.C. § 1396r-8(b)(1)(B).

34. Wyeth has entered into such a Rebate Agreement with the Secretary of Health and Human Services and thus has agreed to comply with the Medicaid Rebate Statute by extending to the Federal and State Governments the benefit of its Best Price for each of its single source and innovator multiple source drugs.

V.
THE FALSE CLAIMS SCHEME

A. Background Regarding the Protonix Contract

35. In or about June of 2001, Wyeth introduced Protonix I.V., the first and only intravenous PPI drug on the market for the treatment of GERD patients who cannot take oral medication. Prior to that time, sales of Protonix Oral, the tablet formulation of the drug introduced the previous year into the extremely competitive PPI market, had been weak. Moreover, in or about March of 2001, competitor AstraZeneca began a nominal pricing campaign to gain access for its second generation PPI drug, Nexium, at hundreds of teaching hospitals nationwide. Part of AstraZeneca's nominal pricing campaign involved switching hospitals from Prilosec to Nexium by

not offering any discounts on Prilosec while providing nominal pricing for Nexium. Pursuant thereto, AstraZeneca salespeople communicated to the hospitals that their PPI budget would be 1/10 of what it was before the switch to Nexium.

36. Within weeks, Wyeth responded to AstraZeneca's nominal pricing strategy for Nexium. Wyeth began to bundle sales of its Protonix I.V. drug with its flagging Protonix Oral drug and offer significant discounts on both Protonix Oral and I.V. to increase sales and market share of the Oral drug. The majority of PPI business is generated in an out-patient setting using the tablet formation, hence, there existed a strong motivation to make sales of the I.V. formulation contingent on achievement of a predetermined Protonix Oral market share, which is what Wyeth did. This marketing scheme, combined with Defendant's off-label promotion of Protonix I.V., *see* section V.E. below, were highly successful in that they led to materially increased sales and market share for Wyeth's Protonix I.V. as well as Protonix Oral.

37. The bundled sales and significant discounts at issue in this case were made pursuant to a Wyeth contract with hospital providers nationwide. The most recent amendment to such contract, the Protonix® Performance Agreement Amendment ("the Protonix Amendment"), is attached hereto as Exhibit A. The original contract which went into effect as early as March 2001, and subsequent amendments are hereby referred to as the "Protonix Contract." The Protonix Contract applies to many hundreds of hospitals and includes for-profit, not-for-profit hospitals and community hospitals. The Protonix Contract is currently in place at Holyoke Hospital in Holyoke, MA, Noble Hospital in Westfield, MA, and at Berkshire Medical Center, in Pittsfield, MA. All of these hospitals routinely treat Medicaid and Medicare patients. Under the Protonix Contract, in exchange for the opportunity to participate in the bundled sales and significant discounts, the

hospital must agree to give the Protonix Oral and I.V. drugs availability on its formulary. A hospital formulary is an approved list of drugs or pharmaceutical products for such hospital. A drug must be available on a hospital formulary if it is to achieve any significant market share in that hospital.

38. Protonix Oral - Pursuant to the Protonix Contract, the following discounts have applied for Oral Protonix:

a. From the effective date of the Protonix Contract until 6/30/03 - guaranteed 94% off of the Protonix Oral catalog price.

b. Starting 7/1/03 - if the hospital's Protonix Oral market share is between 0-19.99%, then no discount off of the catalog price is given. If the hospital's Protonix Oral market share is 20% or greater, the hospital receives 94% off of the catalog price.

39. Protonix I.V. - Pursuant to the Protonix Contract, the following discounts have applied for Protonix I.V.:

a. From approximately 6/1/01 until 1/1/03 - if the hospital achieved a Protonix Oral market share of 60% or greater, the hospital would receive 80% off of the catalog list price of Protonix I.V.

b. Starting 1/1/03 - For each quarter, the discount hospitals receive on the Protonix I.V. ranges from 0% to 80% off of the catalog price depending on the Protonix Oral market share the hospital achieves for the quarter starting six months earlier. The following Discount Grid details the Protonix Oral market share percentages required to earn the Protonix I.V. discounts starting 1/1/03:

DISCOUNT GRID

	QUARTERLY PROTONIX® ORAL MARKET SHARE	SUBSEQUENT PROTONIX® DISCOUNT
Discount Level	From 7/1/02 to 9/30/02 and Each Quarter Thereafter	IV Beginning 1/1/03
1	0-19.99%	0%
2	20-39.99%	25%
3	40-59.99%	50%
4	≥60%	80%

40. It is Relator's understanding that the catalog list price referenced in the Protonix Contract is the drug's reported Wholesale Acquisition Cost ("WAC"), further discussed below.

41. The savings arising from the Protonix Contract can be enormous. For instance, rather than purchasing a Protonix I.V. vial for $20.00, a hospital with the 80% discount could purchase it for $4.00, for a savings of $16.00. This savings would compound rapidly as the number of patients and the number of vials used per patient increased. Notably, the off-label uses of Protonix I.V. (discussed below) involve higher doses and thus more vials.

42. These bundled discounts on Protonix Oral and I.V. are available to hospital purchasers "until June 30, 2005, with the possibility for achieving discounts through December 31, 2005." Further, the Protonix Amendment became automatically effective without a signature for participating hospitals nationwide, unless the hospital opted-out.

B. Wyeth's Nominally Priced/Deeply Discounted Protonix Prices Served as a Disguised Kickback to Hospitals Paid for by the Federal Health Care Programs

43. Federal law, specifically the "Anti-Kickback" statute, 42 U.S.C. § 1320a-7b(b)(2), prohibits the payment of any remuneration to any person in order to induce that person to "purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item" for which reimbursement may be made under a Federal health program. Anyone found guilty of offering or paying kickbacks in violation of the Anti-Kickback statute shall be guilty of a felony.

44. Throughout the relevant time periods detailed above, Wyeth's nominally priced or heavily discounted Protonix Oral and I.V. prices served as a disguised kickback to hospitals financed by the Federal Health Care Programs' reimbursement for drugs, including Medicare and Medicaid.

45. Under the terms of the Protonix Contract, hospitals such as Lahey Clinic Medical Center and Winchester/Hallmark Hospitals, purchased and continue to purchase, the drugs for a small fraction of their catalog prices. For example, in mid-2001 Wyeth offered the Protonix 40 mg. tablet for just $0.15 per pill versus a WAC catalog price of $2.50 per pill. Similarly, since February 2003 the 94% Protonix Oral discount has reduced the price of a Protonix tablet from approximately $2.90 per pill to just $0.17 per pill. Deep discounts also apply to the I.V. The $20 per vial price of Protonix I.V., in effect from at least as early as June 2001 until January 2003, dropped to $4 a vial with the 80% reduction in price. Protonix I.V.'s catalog price since January 2003 has been $22 per vial, however, with the 80% discount, it costs only $4.40 per vial.

46. Pharmacists at hospitals, including at Boston Medical Center and Rhode Island Hospital, have directly communicated to Relator that they intended to purchase Protonix rather than AstraZeneca's Nexium because of the highly reduced prices provided for by the Protonix Contract.

47. The spread between these greatly reduced prices and the reimbursement by Medicare and Medicaid, (*see* section V.C. below regarding falsely inflated reimbursement), induced providers to purchase, prescribe and/or dispense Wyeth's Protonix over competitors' drugs, including H-2 Blockers, and rendered the claims by providers for reimbursement for these drugs false. Indeed, the money which hospitals can receive in benefitting from the spread can be enormous. If a hospital purchased one vial of I.V. for $4.00, it would generally be reimbursed by Medicare and Medicaid in an amount in excess of $20.00, making for a "profit" of at least $16.00 per vial.

48. Throughout the relevant time periods, Wyeth knowingly offered and agreed to nominal and extremely reduced prices for hospitals nationwide as a means to place Protonix on hospital formularies and to drive sales and market share in a competitive PPI market. Specifically, this marketing scheme as set forth in the Protonix Contract influenced, and continues to influence, hospitals' formularies, hospitals' and pharmacies' purchasing patterns and physicians' prescribing decisions. Further, Wyeth was motivated to get patients in hospitals on Protonix thereby increasing the likelihood that it would be prescribed for them at discharge.

49. This marketing scheme as set forth in the Protonix Contract proved successful – according to Wyeth's 2002 Annual Report, Protonix sales in 2002 topped $1 billion and represented 15% of the fiercely competitive national PPI market. In the Boston area, as a result of the success of the Protonix Oral and I.V. marketing campaign, market share for Protonix exceeded 35% for Partners Healthcare and 46% for CareGroup for the first quarter of 2003.

C. Wyeth Submitted Falsely Inflated Price Representations for Protonix Oral and I.V.

50. With respect to covered *out-patient* drugs, Congress has mandated that the Medicare Program pay no more than eighty percent (80%) of the drug's Average Wholesale Price ("AWP") minus 5%. 42 U.S.C. § 1395(l) *et seq.*[3] Drug manufacturers, including Wyeth in this case, supply the published AWP to several nationally recognized drug price compendia including Red Book, First DataBank and Medi-Span. Medicare, directly or through its authorized contractors, then obtains the AWP from such a compendium, generally Red Book, to arrive at a reimbursement amount. These representations are not applicable to drugs administered in an in-patient setting to a Medicare beneficiary because, as noted earlier, Medicare pays a set charge for in-patient care based on the illness being treated.

51. Under 42 C.F.R. § 447.331, with respect to *both* in-patient and out-patient drugs, Medicaid drug reimbursement is to be based upon an estimation of the provider's acquisition cost plus a reasonable dispensing fee. At all relevant times herein, State Medicaid Programs have based their reimbursement for covered drugs, such as those at issue here, on the basis of published prices supplied by drug manufacturers (and contained in drug compendia, First DataBank in particular). These published prices include WAC, AWP and Direct Price. Most State Medicaid Programs rely upon AWP. In the case of a WAC State, a percentage ranging from roughly 5% to12% is added to WAC depending on the State's Medicaid Program. Analogously, in the case of an AWP State, a percentage is subtracted from AWP, ranging generally from 5% to 20%, again depending on the State's Medicaid Program.

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[3]As noted earlier, although Protonix I.V. was a covered drug in an out-patient setting under Medicare, Protonix Oral generally was not.

52. Wyeth has submitted false AWP and WAC price representations for its Protonix Oral (beginning on or around May 2000) and I.V. drugs (beginning on or around June 2001) in order to falsely inflate the Federal Health Care Programs' reimbursement amounts for such drugs.

53. For instance, Wyeth's falsely inflated price representations as reported to the pricing compendium Medi-Span and Red Book are included in Exhibits B and C, respectively, attached hereto. The price representations contained in First DataBank are identical or substantially similar to those in Medi-Span and Red Book. As of April 2002, for example, First DataBank's reported WAC price for the Protonix 40 mg tablet was $2.70. As shown by Exhibits B and C, Wyeth continually increased its AWP and WAC price representations over the relevant time periods.

54. Throughout the relevant time period, Wyeth knew its price representations would be, and in fact were, utilized by the Federal Government and State Medicaid Programs in calculating reimbursement amounts. However, during the relevant time period herein, the actual prices at which the hundreds of hospital providers which had entered into the Protonix Contract routinely acquired Protonix Oral and I.V. reflected deep discounts, including nominal pricing, thereby rendering the published prices materially inflated and not reasonably related to the prices actually being paid for the drugs in the marketplace. Further, Defendant was aware of and monitored the prices actually being paid for its Protonix drugs in the marketplace since this knowledge was necessary to properly perform sales, marketing and manufacturing functions with the company. *See* sections V.A. and V.B. above; *see also* the Protonix Contract.

55. The spread between these greatly reduced prices at which providers acquired the drugs and the drug manufacturers' inflated price representations used by Medicare and Medicaid and other Federal Health Care Programs to reimburse providers, served to induce providers: 1) to

purchase, prescribe and/or dispense Wyeth's Protonix over competitors' PPI and H-2 Blocker drugs with the same clinical efficacy; and/or 2) to purchase, prescribe and/or dispense Wyeth's Protonix Oral and I.V. in greater quantities than medically necessary. Notably, many of these patients could have been adequately treated with I.V. and Oral H-2 Blockers thereby saving significant Medicare and Medicaid dollars. As a result, the Federal Government has suffered damages due to Wyeth's falsely inflated price representations.

D. Wyeth Underpaid its Medicaid Rebates by Improperly Excluding Certain Discounts as Nominal

56. Under the Rebate Program, 42 U.S.C. § 1396r-8(c)(1)(A) and (B), each State's basic rebate amount for each quarterly (three month) rebate period for each dosage, form and strength of a single source drug or innovator multiple source drug has been essentially equal to the greater of: 1) AMP minus the Best Price; or 2) 15.1% of AMP, times the total number of units of the drug reimbursed by the Medicaid Program.

57. Pursuant to 42 U.S.C. § 1396r-8(c)(1)(c), Best Price is generally defined as the "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States" and shall include "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section)" and excludes prices that are "merely nominal in amount." To qualify as "nominal", a price must be less than 10 percent of AMP.

58. Pursuant to 42 U.S.C. § 1396r-8(k)(1), AMP means, during the rebate period, "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts."

59. Manufacturers report their AMP's and BP's to CMS on a quarterly basis. CMS, in turn, calculates the rebate amount as either AMP minus BP (or uses the current 15.1% minimum) for innovator drugs. CMS then forwards the figures by NDC number to each State. Each State then multiplies the rebate amount by the number of units that the State paid for during the quarter for each NDC number to determine the rebate amount due and submits this amount to the manufacturer for payment. The manufacturer remits this payment on a quarterly basis, withholding any disputed amount.

60. Beginning as early as Spring 2001, and continuing through the present, Relator's evidence shows that Wyeth has underpaid its quarterly Medicaid rebates by failing to accurately report its Best Prices to CMS for its Protonix Oral and Protonix I.V. drugs. Wyeth has artificially inflated its Best Price which has enabled Wyeth to pay smaller rebate amounts, to the direct detriment of both the Federal and State Governments, since the Federal and State Governments jointly fund the Medicaid Program.

61. The 94% discount on the price of Protonix Oral, which has been in effect since approximately March 2001, on its face indicates that Wyeth knowingly set its discount at a level intended to permit exclusion of these prices in its Best Price calculation for Medicaid rebate purposes by treating them as nominal under the Medicaid Rebate Program. This fact alone appears to render the nominal price exclusion inapplicable because the nominal pricing is being offered simply to induce sales and increase market share by supplying it cheaply to hospitals nationwide while not affording Medicaid the benefit of such a discount. The nominal price exclusion is intended to allow drug manufacturers to sell their products to research institutions and charitable organizations at very low prices for the sake of the public good without having these prices

considered for Best Price calculation purposes. These "nominal" prices, in contrast, were actually a disguised discount set at levels intended to circumvent the Medicaid Rebate Best Price calculation while simultaneously inducing sales. *See* Office of Inspector General, *Compliance Program Guidance for Pharmaceutical Manufacturers,* April 2003 at II, B, 2, b ("OIG Report"). Tellingly, Wyeth has never offered discounts of any sort on Protonix to the Federal Government pursuant to the Federal Supply Schedule.

62.. Moreover, and in any event, in calculating the Best Price of an innovator drug, any discount in a bundled sale must be allocated proportionately among all drugs sold in the bundle, as the drugs were sold pursuant to the Protonix Contract. Therefore, the discount on the Protonix Oral and I.V should have been proportionately allocated between both drugs in determining each drug's Best Price during each quarter in which the two drugs have been offered in a bundle which resulted in the hospital paying less than if they had bought the two drugs separately.

63. This proportionate allocation of discounts among the bundled drugs would necessarily have had the effect of decreasing the actual Protonix Oral discount so that it would no longer be less than 10% of AMP and thus would have to be included for Best Price reporting purposes. For instance, under the current Protonix Contract, if the hospital purchases enough Protonix Oral to achieve only the 25% discount on the Protonix I.V., it seems inconceivable that a proper, proportionate allocation of the 94% discount on the Oral and 25% discount on the I.V. would do anything but increase the actual Protonix Oral price to something greater than 10% of AMP. Likewise, during the period when a 60% Protonix Oral market share gave rise to an 80% discount off of Protonix I.V., it is more than reasonable to infer that instances exist in which the proportionate allocation of the two discounts was sufficient to render the price of Protonix Oral greater than 10%

of AMP.

64. Additionally, to the extent Wyeth did not proportionately allocate the discounts on the Protonix Oral and I.V., the Best Price of the I.V. was necessarily inflated. For instance, using a previous example, if the discount on the Oral was 94% and the discount on the I.V. was 25%, proportionately allocating the discount would perforce increase the I.V. discount to an amount greater than 25%.

65. By failing to apportion the discount among the Protonix Oral and I.V. drugs, the Federal and State Governments did not receive the benefits of Wyeth's Best Prices on Protonix Oral and I.V. through its Medicaid rebate payments for these drugs. Therefore, Wyeth underpaid its Medicaid rebate payments owed to the States for said drug thereby causing damage to the Federal and State Governments which jointly-fund the Medicaid Program

66. Throughout the relevant time period, Wyeth: 1) knew that CMS used the Protonix Oral and I.V. BP representations it supplied to calculate the rebate amounts; 2) knew that CMS transmitted the rebate amounts to the State Medicaid Programs which then multiplied those figures by the number of units paid for each drug; and 3) knew or recklessly disregarded the fact that the information it had supplied to CMS regarding Best Price of Protonix was false.

E. Wyeth Marketed Its Drug Protonix I.V. For Off-Indication/Label Uses

67. From on or about June 2001 and continuing to the present, Wyeth promoted, marketed and sold, and continues to sell, Protonix I.V. for off-label uses – for instance, for patients with bleeding peptic ulcers – contrary to its FDA-approved indications for treatment of GERD patients who cannot take oral medication and for the extremely rare disease, ZES.

68. Throughout the relevant time period, Wyeth sales representatives have promoted and

marketed Wyeth's Protonix I.V. for off-label uses, for example as part of the regimen for treating bleeding peptic ulcers, in order to increase sales. Wyeth has never received FDA approval to promote Protonix I.V. as part of the treatment for bleeding peptic ulcers, which involves a higher dosing regimen (many more units per patient per day) than the FDA-approved regimen for the treatment of GERD using Protonix I.V. Nevertheless, Defendant has endorsed and caused its sales representatives to promote such use recognizing that the market for an intravenous PPI drug is limited if it is available only for GERD and ZES patients who cannot take oral medication.

69. One marketing tactic employed by Defendant's sales representatives in the Boston area to promote such an off-label use is reliance on a foreign Prilosec I.V. (omeprazole) study (the "Prilosec Study")(Prilosec I.V. is not available in the United States) published in *The New England Journal of Medicine* in August of 2000. *See* Exhibit D attached hereto.

70. The Prilosec Study, conducted at the Prince of Wales Hospital in Hong Kong, determined that the use of a high-dose intravenous infusion of Prilosec (omeprazole) for the treatment of bleeding peptic ulcers "reduced the rate of recurrent bleeding" and "shortened the length of hospitalization" for those patients participating in the study. *Id.* at 315. The Prilosec Study followed a regimen of an 80 mg intravenous injection of Prilosec (omeprazole) followed by injections of 8 mg per hour for 72 hours following the initial injection. In contrast, the protocol approved by the FDA for treatment of GERD patients involves a much lower dose of Protonix I.V. (an infusion of 40 mg/day).

71. Defendant caused its sales representatives to provide the Prilosec Study to hospitals, physicians and pharmacists, including medical personnel employed at hospitals that have signed the Protonix Contract, offering the sales pitch that all PPI's are essentially the same. Therefore,

Defendant's sales representatives go on to claim, because Prilosec I.V. is safe and effective pursuant to the Prilosec Study for the treatment of bleeding peptic ulcers, the same can be said of Protonix I.V. However, what such sales representatives fail to disclose in making such a sales presentation are the material facts that Protonix I.V. and Prilosec I.V. are not the same drug, are not bioequivalent, and are not composed of the same chemical compounds and that therefore any conclusions one can draw from the Prilosec Study as to the safety and efficacy of Prilosec I.V. in treating bleeding peptic ulcers cannot be drawn as to Protonix I.V. on the basis of that study.

72. During the course of Relator's employment at AstraZeneca, she has communicated with various pharmacists including Clinical Pharmacy Managers and Directors of Pharmacy, at Boston-area teaching hospitals (e.g., Boston Medical Center, Rhode Island Hospital) about their decision to purchase a particular PPI drug, including their rationale for purchasing Wyeth's Protonix I.V. Her direct communications with hospital pharmacists and others throughout the relevant time period have revealed that hospitals have bought, and continue to buy, Protonix I.V. for off-label uses. Further, Relator's information that Protonix I.V. is being used for off-indication purposes has been corroborated by AstraZeneca salespeople and medical information scientists across the country.

73. The resulting increase in off-indication sales of the drug throughout the relevant time period has caused harm to the Federal Health Care Programs by increasing the number of claims for reimbursement. Also, since the launching of Protonix I.V., most of the usage of the drug – in the New England area and beyond – involved, and continues to involve, the higher doses required for administering the drug for off-label uses as is the case when the I.V. is used as part of the regimen to treat bleeding peptic ulcers. The treatment of GERD patients, on the other hand, only requires an infusion of 40 mg per day of Protonix I.V. and the treatment of ZES patients, while requiring a

higher dosage, is extremely rare, with hospitals treating about one patient per year. As the majority of Protonix I.V. is, and continues to be, used for off-label purposes, the Wyeth sales representatives' marketing efforts have been proven successful.

74. In sum, Relator alleges: 1) that Defendant promoted, marketed and sold Protonix I.V. for off-label uses; 2) that Defendant's conduct caused hospitals, a) to purchase Protonix I.V. for non-FDA-approved purposes, b) to purchase Protonix I.V. over competitor's less expensive drugs, such as I.V. H-2 Blockers, and c) in significantly larger quantities than they otherwise would have; and 3) that Defendant's scheme caused the Federal Health Care Programs to suffer damages through increased reimbursement, including Medicare and Medicaid reimbursement, for the off-label uses of the drug.

COUNT I

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; ILLEGAL REMUNERATION

75. This is a civil action by the Relator, Lauren Kieff, on behalf of the Plaintiff, the United States, and against Defendant Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

76. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

77. Defendant, from on or around March 2001 with respect to Protonix Oral and from on or around June 2001 for Protonix I.V., and continuing until the present, has knowingly offered and/or paid directly or indirectly, overtly or covertly, in cash or in kind, remuneration to its customers to induce them to purchase, order or arrange for or recommend purchasing or ordering Protonix. Defendant knew that payment would be made, in whole or in part, under a Federal Health

Care Program(s), including by Medicare and State Medicaid Programs. Such illegal remuneration is specifically prohibited by 42 U.S.C. § 1320a-7b(b)(2)(B) and 18 U.S.C § 2.

78. Defendant's knowing and willful actions in offering and/or paying its customers such remuneration prohibited by 42 U.S.C. § 1320a-7b(b)(2)(B), caused the claims for reimbursement for Protonix which the hospitals, physicians and pharmacists presented for payment and approval to a Federal Health Care Program(s), including to the Medicare and States' Medicaid Programs to be false and fraudulent, in violation of 31 U.S.C § 3729(a)(1). In this regard, there exists a strong nexus between compliance with 42 U.S.C. § 1320a-7b(b) and the entitlement to reimbursement under a Federal Health Care Program providing drug cost reimbursement such as Medicare or Medicaid.

79. Because of Defendant's conduct as set forth in this Count, the United States suffered actual damages in excess of One Million Dollars ($1,000,000.00) all in violation of 31 U.S.C. § 3729(a)(1).

COUNT II

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

80. This is a civil action by Relator, Lauren Kieff, on behalf of the Plaintiff, United States, against Defendant Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

81. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

82. From the Spring of 2001, and continuing until the present, Defendant knowingly [as defined in §3729(b)] has made, used and caused to be made or used, false records or statements to

get false or fraudulent claims to be paid or approved by the Government, in that Defendant submitted false information to CMS on a quarterly basis, as set forth herein, regarding the Best Price of its drugs Protonix Oral and I.V. By reporting this false information, Defendant Wyeth underpaid its Medicaid rebate obligation and caused corresponding increases in the periodic calculations of drug reimbursement costs prepared and submitted by each State's Medicaid Program to the federal government pursuant to 42 U.S.C. § 1396(b) (the "Submissions"), which are used by the federal government to calculate the federal funding due each State's Medicaid drug reimbursement program. The Submissions thereby each constitute a false claim pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(2).

83. None of the States or State Medicaid Programs had any knowledge that Defendant had provided to CMS the false information that is the subject of this Complaint, and none of the States or State Medicaid Programs had any knowledge that their respective Submissions were rendered false thereby.

84. Defendant Wyeth knew that the information it supplied to CMS was utilized by the United States and the State Governments to determine the required amount of rebate that each drug manufacturer had to pay to each State's Medicaid Program for Protonix Oral and I.V. Defendant also knew that by submitting the false information at issue here, Defendant fraudulently reduced and underpaid its rebate obligations and caused each State's Submissions to be falsely inflated, thus resulting in great financial loss to both the United States and State Governments.

85. Because of Defendant's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of One Million Dollars ($1,000,000.00), all in violation of 31 U.S.C. § 3729(a)(2).

COUNT III

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO CONCEAL, AVOID, OR DECREASE AN OBLIGATION TO PAY OR TRANSMIT MONEY OR PROPERTY TO THE GOVERNMENT

86. This is a civil action by Relator, Lauren Kieff, on behalf of the Plaintiff, United States, against Defendant Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

87. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

88. From the Spring of 2001, and continuing to the present, Defendant knowingly [as defined in § 3729(b)] has made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. Defendant Wyeth knew its obligation under the Medicaid Rebate Program, 42 U.S.C. 1396r-8, to make and use truthful records or statements regarding its drugs. Defendant also knew that the information it periodically submitted to CMS regarding the Best Price of Protonix Oral and I.V. was utilized by the United States and the State Governments to determine the required amount of rebate that Wyeth had to pay to each State's Medicaid Programs for Protonix Oral and I.V. Defendant has made, used or caused to be made or used, false records or statements regarding Protonix Oral and I.V. in order to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State Medicaid Programs, which are jointly funded by the United States and the States, thus directly resulting in great financial loss to the United States and the State Governments. Defendant has caused and continues to cause false statements and records to be made or used to decrease its Medicaid Rebate obligation to pay money or property to the federally funded State Medicaid Programs by falsely overstating its Best Price with respect to Protonix Oral and I.V. in its quarterly

rebate submissions to CMS. By engaging in the conduct outlined above, Defendant thus has caused great financial loss to the United States and the State Governments.

89. Because of the Defendant's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of One Million Dollars ($1,000,000.00), all in violation of 31 U.S.C. § 3729(a)(7).

COUNT IV

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS

90. This is a civil action by the Relator, Lauren Kieff, on behalf of the Plaintiff, the United States, and against the Defendant Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

91. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

92. From on or around March 2001 with respect to Protonix Oral and from on or around June 2001 for Protonix I.V., Defendant knowingly [as defined in §3729(b)] has caused to be presented to officers or employees of the United States and State Governments false or fraudulent claims for payment or approval, in that Wyeth caused to be presented to officers or employees of the United States and State Governments false or fraudulent price and cost information for Protonix Oral and I.V. and caused the United States and State Governments to pay out sums of money to the providers and suppliers of said drugs, materially in excess of the amounts permitted by law, resulting in great financial loss to the United States and State Governments.

93. Because of Defendant's conduct as set forth in this Count, the United States suffered actual damages in excess of One Million Dollars ($1,000,000.00) all in violation of 31 U.S.C. § 3729(a)(1).

COUNT V

FALSE CLAIMS ACT; MAKING, USING, OR CAUSING TO BE MADE OR USED, A FALSE RECORD OR STATEMENT TO GET A FALSE OR FRAUDULENT CLAIM PAID OR APPROVED BY THE GOVERNMENT

94. This is a civil action by Relator, Lauren Kieff, on behalf of the Plaintiff, United States, against Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

95. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

96. From on or around March 2001 with respect to Protonix Oral and from on or around June 2001 for Protonix I.V., Defendant knowingly [as defined in §3729(b)] has made, used or caused to be made or used, false records or statements to get false or fraudulent claims to be paid or approved by the United States and State Governments, in that Defendant caused false records or statements of prices and cost of Protonix Oral and I.V. to be used by the Federal and State Governments to pay or approve claims presented by the providers and suppliers of said drugs, which claims were materially in excess of the amounts permitted by law, resulting in great financial loss to the United States and State Governments.

97. Because of Defendant's conduct as set forth in this Count, the United States and the State Governments suffered actual damages in excess of One Million Dollars ($1,000,000.00), all in violation of 31 U.S.C. § 3729(a)(2).

COUNT VI

FALSE CLAIMS ACT; CAUSING PRESENTATION OF FALSE OR FRAUDULENT CLAIMS; OFF-LABEL MARKETING

98. This is a civil action by the Relator, Lauren Kieff, on behalf of the Plaintiff, the United States, and against Defendant Wyeth under the False Claims Act, 31 U.S.C. §§ 3729-3732.

99. Relator realleges and incorporates by reference paragraphs 1 through 74 as if fully set forth herein and further alleges as follows:

100. Defendant, from on or around June 2001 and continuing through the present, has knowingly promoted, marketed and sold Protonix I.V. for off-label uses contrary to the prohibitions of 21 U.S.C. § 331(a) & (d). In particular, Defendant, through its representatives, has promoted and marketed Protonix I.V. by using the Prilosec Study which involves a different drug (omeprazole I.V.) and different dosing regimen (80 mg) than the regimen for which Protonix I.V. is FDA-approved, to induce hospitals, physicians and pharmacists to purchase and use Protonix I.V. for a non-FDA approved indication (such as the treatment of bleeding peptic ulcers). By using the Prilosec Study to market Protonix I.V. off-label, Defendant has made numerous fraudulent statements about the safety and efficacy of said drug for the treatment of bleeding peptic ulcers and has caused the submission of numerous off-label prescriptions for said drug for reimbursement by the Federal Health Care Programs, including by Medicare and Medicaid.

101. Defendant's off-label marketing in violation of 21 U.S.C. § 331(a) & (d), has caused the off-label claims for reimbursement for Protonix I.V. to be false and fraudulent, in violation of 31 U.S.C § 3729(a)(1). In this regard, there exists a strong nexus between compliance with 21 U.S.C. § 331(a) & (d) and the entitlement to reimbursement under a Federal Health Care Program providing drug cost reimbursement such as Medicare or Medicaid.

102. Because of Defendant's conduct as set forth in this Count, the United States suffered actual damages in excess of One Million Dollars ($1,000,000.00) all in violation of 31 U.S.C. § 3729(a)(1).

REQUESTS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in its favor and against Defendant Wyeth for the amount of damages on each Count (Counts I through VI total) for three times the amount of damages to the Federal Government and State Governments, plus civil penalties of no more than Eleven Thousand Dollars ($11,000.00) and no less than Five Thousand Five Hundred Dollars ($5,500.00) for each false record or statement made, used, or caused to be made or used.

Further, Relator, on her behalf, requests that she receive the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the UNITED STATES, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that her award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

Dated: November 24, 2003

Respectfully submitted,

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